DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 7, 2016

Biotronik, Inc.
Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K160985
Trade/Device Name: Pantera Pro Coronary Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: September 1, 2016
Received: September 6, 2016

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160985

Device Name
Pantera Pro Coronary Dilatation Catheter

Indications for Use *(Describe)*
The Pantera Pro is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Pantera Pro (balloon diameter 2.0 – 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary per 21 CFR 807.92

Date Prepared:	March 9, 2016
Applicant:	BIOTRONIK, Inc. 6024 Jean Road Lake Oswego, OR 97035
Contact Person:	Jon Brumbaugh Vice President, Regulatory Affairs and Compliance Phone: (888) 345-0374 Fax: (503) 635-9936 jon.brumbaugh@biotronik.com
Proprietary Name:	Pantera Pro Coronary Dilatation Catheter
Common Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter
Device Classification:	Class II (special controls)
Regulation Number:	870.5100
Classification Name:	Catheter, transluminal coronary angioplasty, percutaneous
Product Code:	LOX
Device Description:	BIOTRONIK's Pantera Pro is a sterile, single-use, intravascular balloon catheter for the dilatation of stenotic segments in coronary arteries or bypass grafts. The dilatation balloon is designed to inflate to a known diameter and length at a specific inflation pressure. Pantera Pro has balloon diameters ranging from Ø 1.25 mm – 4.0 mm and balloon lengths ranging from Ø 6 mm – 30 mm. All product sizes of Pantera Pro have a usable catheter length of 140 cm. The Pantera Pro has a soft tapered tip at the distal end of the catheter to facilitate advancement of the catheter. The balloon is folded to achieve a low crossing profile and is connected to the tip. The Pantera Pro has two coatings; a hydrophobic coating on the outer surface of the hypotube and a hydrophilic polymeric based coating on the outer surface of the distal outer shaft. In addition, a hydrophobic coating is applied on the balloons of sizes Ø 2.5 – 4.0 mm whereas a hydrophilic coating is applied on the balloons of sizes Ø 1.25 mm – 2.0 mm. The coating is activated by immersing the catheter in sterile saline prior to use. The Pantera Pro is compatible with guide wires of 0.014" (0.36 mm) diameter and guiding catheters with an inner diameter of ≥0.056" (1.42 mm; 5F). For all Pantera Pro product sizes, the nominal pressure (NP) required to achieve the nominal diameter is 7 atm and the rated burst pressure (RBP) is 14 atm.
Indications For Use:	The Pantera Pro is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The Pantera Pro (balloon diameter 2.0 – 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents.
Predicate Device(s):	Medtronic Sprinter Legend (P790017 /S096 & K103095) Boston Scientific Maverick^2 (P860019 / S179).

Comparison of Technological Characteristics

Pantera Pro has the same intended use as the predicate devices. The materials, design, and performance characteristics are similar. Balloon lengths and diameters are within the same range as the Medtronic Sprinter Legend. Pantera Pro has a consistent nominal pressure (7 atm) and rated burst pressure (14 atm) across the entire size range whereas the predicates vary. As described in the device description, Pantera Pro has hydrophilic or hydrophobic balloon coating depending on balloon diameter. Sprinter Legend balloons have hydrophilic coating and Maverick^2 have hydrophobic. All devices are sterilized by EO gas sterilization.

Summary of Non-Clinical Data

Design Verification in-vitro testing:

The following in-vitro bench tests were completed on the Pantera Pro in accordance with the requirements of Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010, and verify that it meets the required performance specifications.

- Dimensional Verification (including visual inspection)
- Balloon Preparation, Deployment and Retraction
- Balloon Rated Burst Pressure
- Balloon Fatigue
- Balloon Compliance
- Balloon Inflation and Deflation Time
- Catheter Bond Strength
- Tip Pull Test Flexibility and Kink Test
- Torque Strength
- Radiopacity Coating Integrity
- Particulate Evaluation
- Shelf Life testing was provided to support a 3 year shelf life.

Additional Tests for Catheters Intended for Post-Delivery Expansion of Balloon Expandable Stents:

- Balloon Rated Burst Pressure in Stent
- Balloon Fatigue / Repeat Balloon Inflation in Stent

Biocompatibility Testing:
Biocompatibility testing for the Pantera Pro has been completed in accordance with the recommendations of Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010, and International Standard ISO10993- 1:2009, Biological Evaluation of Medical devices- Part 1: Evaluation and Testing for an external communicating device with limited exposure (i.e. whose contact with circulating blood is ≤ 24 hours). The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Hemolysis
- Complement activation
- In Vivo Thrombogenicity
- Hemocompatibility – Chandler Test
- Bacterial Reverse Mutation Assay – AMES test
- Mouse Lymphoma Assay
- Mammalian Micronucleus Test

The Pantera Pro Dilatation Catheter met all specified design and performance requirements. No new safety or effectiveness issues were raised during the testing. The bench testing validation and biocompatibility testing demonstrated that the Pantera Pro is substantially equivalent in terms of safety and effectiveness to the predicate device.

Summary of Clinical Data: No clinical investigation has been performed for this device.

Sterilization: The Pantera Pro catheter is provided sterile to the user. Pantera Pro is sterilized with EO gas to achieve a sterility assurance level (SAL) of 1×10^{-6}. The device meets the endotoxin limit of 20 EU / device.

Conclusion: The intended use of the subject Pantera Pro, as described in the labeling, is the same as the predicate devices Sprinter Legend RX (P790017 / S096 & K103095) and Maverick^2 (P860019 / S179). In addition, the indications for use are similar and the fundamental technology has not changed. Minor differences have been evaluated through performance testing that shows the Pantera Pro meets performance specifications. The biocompatibility testing shows the materials of construction are biologically safe for the intended use. Therefore, Pantera Pro is considered substantially equivalent to the predicate device.